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## PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

33677.00700US

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on \_\_\_\_\_

Signature \_\_\_\_\_

Typed or printed name \_\_\_\_\_

Application Number

10/040,830

Filed

01/08/2002

First Named Inventor

Borodic

Art Unit

1645

Examiner

Vanessa L. Ford

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.☐ assignee of record of the entire interest.  
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.  
(Form PTO/SB/96)☒ attorney or agent of record. 47,304  
Registration number \_\_\_\_\_☐ attorney or agent acting under 37 CFR 1.34.  
Registration number if acting under 37 CFR 1.34 \_\_\_\_\_  
Signature

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Typed or printed name

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Telephone number

April 18, 2006

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below\*.

☐ \*Total of \_\_\_\_\_ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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U.S. Application Serial No. 10/040,830  
Attorney Docket No.: 33677.00700

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:	)	
	)	
Gary E. BORODIC <i>et al.</i>	)	
	)	
Application Serial No.: 10/040,830	)	Group Art Unit: 1645
	)	
Filed: January 8, 2002	)	Examiner: Vanessa L. Ford
	)	
Title: <i>The Use of Botulinum Toxin For The</i>	)	
<i>Treatment of Chronic Facial Pain</i>	)	

**MAIL STOP AF**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Sir:

In response to the Final Office Action mailed January 18, 2006, Applicants respectfully submit the following Pre-Appeal Brief Request for Review. A Notice of Appeal is filed concurrently herewith with the required fee.

Applicants respectfully submit that the rejections of record are clearly improper because essential elements required to establish a prima facie case have been omitted. The rejections of record are based on errors in facts and should be withdrawn. Applicants amended the claims and provided a detailed explanation of the bases for traversing the pending rejections in the Amendment And Response filed October 12, 2005. The Final Office Action mailed January 18, 2006 dismissed the Amendment without addressing the limitation "identifying a subject with facial pain caused by trigeminal neuralgia in need of treatment thereof," which is not disclosed either explicitly or inherently by any of the references of record. Withdrawal of the outstanding rejections and allowance of the claims is therefore requested.

*The Rejection of Claims 16-19 under 35 U.S.C. § 102(b)*

Claims 16-19 stand rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. No. 5,714,468 to Binder (the '468 patent). Applicants respectfully traverse this rejection for the following reasons.

Applicants amended claim 16 in the Amendment And Response filed October 12, 2005. The Amendment added the limitation "identifying a subject with facial pain caused by trigeminal neuralgia in need of treatment thereof." The '468 patent does not teach – inherently or otherwise – this limitation of the claimed invention, and this limitation is not addressed by the Examiner in any of the Office Actions of record. Contrary to the Examiner's assertions, the '468 patent does not teach or disclose treating facial pain caused by trigeminal neuralgia with botulinum toxin. As previously explained in the October 12, 2005 Amendment And Response, the '468 patent is directed to the treatment of headache pain. At the very most, the '468 patent may disclose treatment of headache pain related to trigeminal neuralgia, but this is simply not the same as, or anticipatory of, treating facial pain caused by trigeminal neuralgia, which is clinically distinct. It is therefore respectfully asserted that the '468 patent is improperly applied against the pending claims because it does not teach, inherently or explicitly, each and every element of the pending claims.

The '468 patent is directed to methods for the treatment of headache pain. Headache pain is not the same as facial pain caused by trigeminal neuralgia. See Applicant's detailed discussion of Example 1 on page 7-8 of the October 12, 2005, Amendment And Response. The '468 patent does not teach treating facial pain caused by trigeminal neuralgia. More specifically, the '468 patent does not mention diagnosis or identification of patients suffering from facial pain caused by trigeminal neuralgia in need of treatment thereof. Thus, the '468 patent does not and cannot disclose identifying a subject with facial pain caused by trigeminal neuralgia in need of treatment thereof. Therefore, the '468 patent does not teach, inherently or explicitly, each and every element of the pending claims.

Moreover, as previously explained, the '468 patent does not teach treating facial pain caused by trigeminal neuralgia. The Examiner apparently continues to assert that headache pain and the treatment thereof is the same as, or inherently the same as, facial pain caused by trigeminal neuralgia and the treatment thereof. See Examiner's Response in the Final Office Action of January 18, 2006, at page 5 – "It is the Examiner's position that the prior art teaches: a patient that has trigeminal neuralgia and the art teaches the patient has pain associated with trigeminal neuralgia." Basing the rejection of the pending claims on this assertion is clear error and a misinterpretation of the facts. The "pain associated with trigeminal neuralgia" as described in the '468 patent is headache pain, not facial pain. This error has been addressed by applicants on multiple occasions (see above), in multiple responses and interviews with the Examiner and others at the USPTO. Nowhere does the '468 patent address treatment of facial pain caused by trigeminal neuralgia. The Examiner asserts that: "Binder further teaches that patients that have pain related to for example, trigeminal neuralgia was reduced" (see Office Action of January 18, 2006, at page 7 (emphasis in original)). This is at best an inaccurate statement of the disclosure in Binder. Binder states at col. 6 that:

For example, as shown in the data presented in the Examples, the method of the invention was effective in reducing headache pain even in persons who only received an extramuscular injection of presynaptic neurotoxin. Moreover, reduction of headache pain was unexpectedly observed even in patients whose pain was causally related to vascular or neurological components; e.g., classical migraine, trigeminal neuralgia and trauma headache. However, those of ordinary skill in the art will recognize that additional therapeutic benefits may be achieved through introduction of the presynaptic neurotoxins of the invention into musculature (particularly in the back) where muscle spasm or strain is present.

U.S. Pat. No. 5,714,468 to Binder at Column 6 (emphasis added).

As can be clearly seen from the actual text of column 6 of the '468 patent, the discussion is concerned with headache pain. There is no mention of facial pain caused by trigeminal neuralgia or the treatment thereof. Neither is there any mention of the identification of a subject with facial pain caused by trigeminal neuralgia in need of treatment thereof.

To summarize, the '468 patent does not teach identifying a subject with facial pain caused by trigeminal neuralgia, or the treatment of facial pain caused by trigeminal neuralgia. At best, the '468 patent teaches the use of Botulinum toxin to treat headache pain, but this is simply not the same as what Applicants have invented and currently claim. Consequently, the '468 patent does not anticipate claims 16-19. Reconsideration and withdrawal of the rejection is requested.

### *Specification*

The Specification stands objected to. Applicants previously amended the specification as suggested by the Examiner to capitalize all uses of trademarks. The Examiner now requests that the Applicants include the use of trademark symbols associated with these marks. Such use of trademark symbols is unnecessary and is not required. However, in the interest of expediting prosecution, if this objection is maintained, these symbols will be added by amendment to the specification, once the other rejections have been withdrawn. Withdrawal of the objection is requested.

***Conclusion***

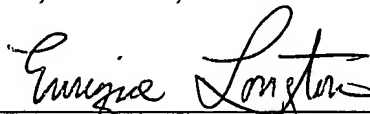
Applicant believes that the above-referenced application is in condition for allowance. Reconsideration and withdrawal of the outstanding rejections and objections and notice of allowance to that effect is respectfully requested.

The Commissioner is authorized to charge any additional fees associated with this filing, or credit any overpayment, to Deposit Account No. 13-3250. **EXCEPT** for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 13-3250. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with C.F.R. § 1.136(a)(3).

Respectfully submitted,

**MILBANK, TWEED, HADLEY & McCLOY LLP**

By: \_\_\_\_\_



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Dated: April 18, 2006

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